

Application/Control Number : 10/691,589  
Art Unit: 3736  
January 30, 2006  
Page 5

### Remarks

The Examiner's comments and objections and the cited references have been carefully considered by the Applicant.

Reconsideration of the application as hereby amended is respectfully solicited.

The title has been changed as suggested by the Examiner.

### Claim Rejections under 35 USC § 102

Original claims 1 and 2 have been canceled without prejudice.

New independent claims 3, 10 and 11 and dependent claims 4-9 are herewith submitted for examination.

Rilliet discloses in Figure 3 and related description of columns 5-6, lines 40-68 and 1-3, respectively,

*a stopper 22 with a hollow head incorporating a chamber 23 closed by a flexible outer end wall 24 with a central slot 26 defined between two flexible lips 25a, 25b of the wall, which resiliently retain the rubber sleeve 3 of the needle pre-inserted into the stopper, as a pre-assembled unit so as to avoid tedious pre-puncture of the membrane 6 of the stopper; by such resilient pressure retaining action, the blood collection unit 9 remains strongly assembled with the needle holder and holder 1.*

The new claims as are now pending in for examination, are drawn instead to a

"stopper... (with) an external face thereof with a piercing guiding point."

"the piercing guiding point suitable for a hollow needle to pierce axially therein and

Application/Control Number : 10/691,589  
Art Unit: 3736  
January 30, 2006  
Page 6

further through said stopper for blood collection into the tube" ,

"an annular lip that is formed monolithic with said stopper so as to protrude radially from said peripheral region over said external face of the stopper, towards said central region thereof and up to and around said opening ", and

"an annular groove that is formed under said annular lip and between said annular lip and said external face and surrounds said piercing guiding point, said groove being shaped so as to retain and contain any blood drop that is entrained out of the tube and through the stopper upon withdrawal of the needle from the stopper" (Claim 3).

In addition, in Claim 10,

the external face of the stopper has a

" central region being provided with an opening suitable to allow free passage of the needle piercing end covered by the elastic sheath to said piercing guiding point".

And in Claim 11:

"an external cavity that is formed on said front-external face of the stopper and has a peripheral edge, said piercing guiding point being located in said cavity; an annular lip that is formed monolithic with said stopper so as to protrude radially inwardly from said peripheral edge of the cavity, over said external face of the stopper and towards said central region thereof and up to and around said opening; and an annular groove that is formed in said cavity, under said annular lip and between said annular lip and said external face and surrounds said piercing guiding point".

The arrangement of Rilliet moreover appears unsuitable and disadvantageous in the case in which the blood collection unit has to be changed, with the needle arrangement still inserted into the vein of a patient, for collecting a different blood sample for a different blood determination. Indeed, detaching of the collection unit 9 and stopper 22 from the needle for replacement and a new collection, in view of the resilient retaining of the rubber sleeve 3, appears highly traumatic for a patient.

Vein insertion of the pre-assembled unit, having large radial dimensions, is also difficult to carry out in a non-traumatic manner for the patient.

Application/Control Number : 10/691,589  
Art Unit: 3736  
January 30, 2006  
Page 7


It is further believed that the teaching of Rilliet to the providing of the needle already inserted into the stopper as pre-assembled unit that advantageously makes unnecessary a needle piercing action of the stopper for starting blood collection, after the needle is inserted into the vein, would teach away the one skilled in the art from modifying the arrangement of Rilliet to provide a piercing guiding point into the front external face opening and an opening that provides no resilient pressure retaining of the needle sheath.

Accordingly, it is believed that cited prior documents do not teach or suggest the combination of features recited in the new main claims.

Favorable action is respectfully solicited.

While it is believed that the amended claims properly and clearly define the present invention, applicant would be open to any suggestion or amendment the Examiner may have or propose concerning different claim phraseology which, in the Examiner's opinion, more accurately defines the present invention.

Respectfully submitted,

  
Albert JOSIF (Reg. No. 22,917)  
Agent for the Applicant

Date: January 30, 2006  
Address: Via Meravigli 16, 20123 MILAN-ITALY  
Telephone: (from USA) (011)(39)(02) 8590-7777  
Telefax: (from USA)(011)(39)(02) 863-860